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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,896	08/31/2001	Kevin P. Baker	P2548P1C19	5992

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,896	BAKER ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-35 and 38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-35 and 38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 22-35 and 38-43 are pending in the instant application. Claims 25-34 and 38 have been amended, claims 22, 23 and 35 have been canceled and claims 42 and 43 have been added as requested by Applicant in the Paper filed December 24, 2003.

All claims are currently under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3.1 Claim 42 is indefinite because it encompasses a nucleic acid encoding a polypeptide comprising the sequence of SEQ ID NO: 50 with conservative amino acid substitutions, and there is no limitation as to the number of substitutions that can be made. The claim is indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The language of the claims does not place an upper limit on the extent of the changes to be made, and therefore, the claims fail to adequately point out that which Applicant sees as the invention.

3.2 Claim 43 is indefinite because it encompasses a nucleic acid encoding a polypeptide comprising the sequence of SEQ ID NO: 50 with 0-10 amino acid additions or deletions, and it is not clear if it is 0-10 deletions or a deletion of 0-10 amino acids that is being claimed. Wording such as the following is suggested:

"An isolated nucleic acid encoding a polypeptide comprising the sequence of SEQ ID NO: 50, with the exception that the polypeptide have a deletion or addition of 1-10 amino acids, or 1-10 amino acid substitutions, compared to the polypeptide of SEQ ID NO: 50."

Maintained rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-26, 35 and 38-41 remain rejected and new claims 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Actions, Paper No. 10, at pages 6-8, Paper No. 12 at pages 8-9, and below.

Applicants traverse the rejection on pages 13-17 of the response and submit that the claims are adequately described in the present application, and that the claims have been clarified by the limitation that the claimed nucleic acid is amplified in lung and/or colon tumors. Applicants cite Vas-Cath, Inc. v. Mahurkar and Amgen Inc. v. Chugai Pharmaceutical Co. as

support for Applicants' possession of the claimed invention. Applicants assert that compliance with the written description requirement does not require an application to describe exactly the subject matter claimed, and the present situation is analogous to Example 14 on pages 53-55 of the Written Description Training Materials. Applicants also assert that as the claimed nucleic acids do not have substantial variation (i.e. at least 95% sequence identity), share the biological function of being amplified in lung and/or colon tumors, and the specification teaches assays for identifying nucleic acids, the claims satisfy the written description requirements of 35 U.S.C. 112.

Applicants' arguments have been fully considered but are not deemed persuasive. The present situation is more analogous to Example 11 of the Written Description Training Materials (pages 41-46), which are drawn to allelic variants. Although claim one, drawn to a DNA that encodes protein X was deemed to have meet the written description requirements, that was because the function of the protein was known and had a specific and substantial utility, so that any degenerate DNA encoding the protein met the written description requirement. The instant situation differs from that, in that the function of the encoded protein is not known, the utility is based on amplification of the DNA in tumors, and so any polynucleotide encoding the protein has not meet the written description requirement. Only one polynucleotide in the instant application has been disclosed. In the instant application, the claims are more analogous to claims 2 and 3 in Example 11, which were not found to meet the written description requirement. Claim 2 encompassed an isolated allele of the DNA that encodes protein X, which is similar to claim 27, for example, which claims nucleic acid encoding a polypeptide of SEQ ID NO: 50, and was not found to meet the written description requirement, even though it encodes the same

protein. Claim 3, drawn to an allele of the DNA, which is similar to claim 25, for example, which claims nucleic acid encoding a polypeptide having at least 95% identity to SEQ ID NO: 50, which encompass alleles of the protein and DNA. Claim 3 was not found to meet the written description requirement, since one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the genus and is insufficient to support the claim. In the instant case only one single sequence has been disclosed, and there is no evidence in the specification that other embodiments exist.

Additionally, Applicants assert on page 16 of the response that the specification describes conventionally known methods used and known in the art for preparing a multitude of variants. Applicants' arguments have been fully considered but are not deemed persuasive, because due to the limitation in the claims that the nucleic acid is amplified in lung or colon tumors, these would be naturally occurring nucleic acids, and would not be engineered nucleic acids.

For these reasons the rejection under 35 U.S.C. 112 is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 25-27, 31, 35 and 38-41 remain rejected and new claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Holtzman et al., US Patent Application Publication

US20020028508, effective filing date, April 23, 1998 (09/065,661), for reasons of record in the previous Office Action, Paper No. 12, at pages 4-5, and below.

New claim 43 encompasses isolated nucleic acid encoding a polypeptide comprising the sequence of SEQ ID NO: 50 with 0-10 amino acid deletions or substitutions, wherein the nucleic acid is amplified in lung or colon cancers. The protein of Holtzman is identical to the protein of SEQ ID NO: 50 except for three substitutions and a deletion of 9 amino acids and therefore anticipates the invention.

Applicants' arguments and citation of *Elan Pharm., Inc. v. Mayo Found. For Med. Ed. And Research*, and *Amgen, Inc. v. Hoeschst Marion Roussel, Inc.*, on pages 7-8 of the response that Holtzman et al. does not anticipate the claimed invention because it is not enabling (does not have either a specific and substantially utility or a well-established utility), have been fully considered but are not deemed persuasive. In case *Elan Pharm., Inc. v. Mayo Found. For Med. Ed. And Research*, the issue was whether or not one of ordinary skill could make a desired mutated mouse without undue experimentation (pages 1377-1378). In the instant case, Holtzman et al. describes the nucleic acid by sequence, teaches how to make the nucleic acid, and is therefore an enabling disclosure. According to the language of 35 USC § 102(e), "the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent".

Applicants' arguments and citation of *Verdegaal Bros. V. Union Oil Co. of California* on pages 8-9 of the response that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference, and that Holtzman et al. neither explicitly nor inherently discloses nucleic acids that are amplified,

have been fully considered but are not deemed persuasive. Although Holtzman et al. is silent with respect to amplification of the nucleic acid in tumors, since the nucleic acid of Holtzman et al. is apparently a splice and/or allelic variant of the nucleic acid of SEQ ID NO: 49 of the instant invention, absent evidence to the contrary, it would also be amplified in lung or colon tumors. This would be an inherent property of the nucleic acid (Ex parte Novitski, 26 USPQ2d 1389). Even if it were determined that the nucleic acid of Holtzman et al. is not amplified in tumors, it would still anticipate the claims, because discovering a new biological activity for a compound known in the prior art does not make that compound patentable.

It is believed that all pertinent arguments have been answered.

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER